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March 24, 2000

BY HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

**Re: Citizens Petitions; Actions that Can Be Requested by
Petition, Denials, Withdrawals, and Referrals for Other
Administrative Action (Docket No. 99N-2497); 64 Fed. Reg.
66822 (November 30, 1999)**

Dear Sir or Madam:

The American Frozen Food Institute (AFFI or the Institute) appreciates this opportunity to comment on the Food and Drug Administration's (FDA) proposed rule to amend the agency's longstanding rules concerning citizen petitions. AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's more than 550 members are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than \$60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution and sale of products nationally and internationally.

As food processors, AFFI members are directly regulated by FDA. It is critical, therefore, that they have the opportunity to communicate with the agency and to request agency action when necessary. The citizen petition process has been a very effective mechanism for seeking appropriate changes in FDA regulation and policy. Although AFFI commends the agency for attempting to make the process more efficient, amending the citizen petition rules as proposed will inhibit rather than enhance public participation in agency deliberation.

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FDA's proposed modifications to the citizen petition process would significantly narrow the circumstances in which such petitions would be accepted by the agency for consideration on the merits. The proposal would also permit the agency to issue "brief denials" of citizen petitions in certain circumstances. The agency describes petitions that do not raise a significant public health issue and, specifically, petitions to amend or establish common or usual name regulations or standards of identity, as examples of the types of petitions that would be appropriate for such brief denials.

AFFI opposes restricting the scope of the citizen process and is particularly troubled by the implication in the proposed rule that citizen petitions are appropriate only to address significant public health issues. This approach would threaten industry's ability to experiment with and improve standardized foods. Unless companies can petition the agency for amendment or revocation of common or usual name regulations and standards of identity, existing regulations and standards of identity will remain in their current form indefinitely, leaving no room for innovation. In effect, the regulations will hold both companies and consumers "hostage" by denying any formal process to pursue changes. AFFI, therefore, strongly urges the agency not to adopt any requirement, whether implicit or explicit, that citizen petitions present issues of significant public health before they may be considered.

AFFI is also troubled by the so-called "conforming" amendment in the proposal that would permit FDA to "act upon" rather than "rule upon" every citizen petition. Properly filed citizen petitions deserve consideration and a response by FDA on the merits, even if the response is "no." The language of FDA's regulations should reinforce not undercut this important policy.

AFFI is aware that FDA's resources are limited and its statutory mandates numerous and wide-ranging. The Institute, therefore, supports measures that enable the agency to use its resources in the most effective and efficient manner possible. As a practical matter, however, the proposal would do little if anything to further this goal. The proposed modifications would not prevent the filing of frivolous petitions or petitions that request actions the agency cannot take legally or would not consider for good policy reasons. And, despite the changes the agency proposes, FDA would still have to review these petitions, decide which to accept or reject, and respond.

The existing rules governing citizen petitions have provided a workable system for ensuring effective public participation in the agency's rulemaking and related processes for more than 20 years. Instead of proposing to change a largely successful system, AFFI respectfully suggests that the agency's limited resources

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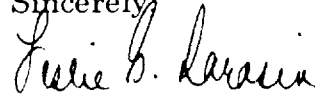
March 24, 2000

Page 3

would be more productively used in refining its citizen petition review process and implementing it more efficiently, through management changes and other, internal modifications.

AFFI appreciates this opportunity to comment on the proposed rule.

Sincerely,

A handwritten signature in cursive script, appearing to read "Leslie G. Sarasin".

Leslie G. Sarasin, CAE

President and Chief Executive Officer